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OPTUNE GIO™ (NovoTTF™ 200A)

User Manual

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This manual is intended for patients receiving TTFields treatment using the Optune Gio treatment kit with Optune HFE transducer arrays (Sterile).

1. ABOUT THE OPTUNE GIO TREATMENT KIT

Optune Gio is a portable medical device which delivers alternating electric fields, called Tumor Treating Fields ("TTFields") in the brain using Optune HFE transducer arrays. TTFields are intended to kill cancer cells. The TTFields are transmitted at a frequency of 200 kHz and up to 707mA RMS output current.

Your doctor has prescribed Optune Gio Treatment Kit for use at home. You may be able to use Optune Gio Treatment Kit on your own, or you may need help from a doctor, family member, or other caregiver. Use Optune Gio Treatment Kit as many hours per day as possible, at least 18 hours per day. Only take short breaks for personal needs.

Optune Gio Treatment Kit is portable and has the ability to run on batteries. You can continue your normal daily life while carrying the device in a shoulder bag or backpack. The Treatment Kit includes four rechargeable batteries. Each battery will last for up to two or three hours. For sleeping, or other times when you plan to stay in the same place for a while, plug the device power supply into a standard wall outlet.

Optune Gio does not need regular maintenance. The Optune Gio treatment kit also does not have any settings for you to change.

The only things you need to do are check that the device has a power source connected (a charged battery plugged into the device, or is connected to a power supply plugged into the wall) and turn it on and off. If the device is not working, an audible error indicator will beep.

A simple Troubleshooting Guide is provided in this manual (Section 24). You can also call the 24-hour technical support telephone number (Section 26).

Shave your scalp and change the Optune HFE transducer arrays twice a week. Keep periods of time off from treatment to a minimum.

Interrupt treatment only for personal needs such as bathing, exercise, or any time where the device may be a distraction. Stop treatment to replace the Optune HFE transducer arrays.

To take a shower, unplug the Optune HFE transducer arrays from the device (leave the Optune HFE transducer arrays on your head) and put a shower cap on your head so they do not get wet. You can take a full shower and wet your head when you are not wearing the Optune HFE transducer arrays (for example, when you have taken them off but before replacing them with a new pair). You can wear a wig or hat over the Optune HFE transducer arrays, if you wish.

2. INTENDED PURPOSE

The Optune Gio Treatment Kit is intended for the treatment of patients with newly diagnosed WHO grade 4 glioma and for the treatment of patients with recurrent WHO grade 4 glioma.

Newly diagnosed WHO grade 4 glioma

Optune Gio is intended for the treatment of adult patients (18 years of age or older) with newly diagnosed WHO grade 4 glioma, following maximal debulking surgery or biopsy, radiation therapy and/or chemotherapy, concomitant with maintenance Temozolomide with or without Lomustine, and after systemic therapy is stopped.

Recurrent WHO grade 4 glioma

Optune Gio is intended for the treatment of patients with recurrent WHO grade 4 glioma who have progressed after surgery, radiotherapy and chemotherapy treatment for their primary disease. The treatment is intended for adult patients, 18 years of age or older.

3. CONTRAINDICATIONS, WARNINGS, PRECAUTIONS AND NOTICES

CONTRAINDICATIONS

Do not use the Optune Gio treatment kit if you are pregnant, think you might be pregnant, or are trying to get pregnant. If you are a woman who is able to get pregnant, you must use birth control when using the device. The Optune Gio treatment kit was not tested in pregnant women.

Do not use the Optune Gio treatment kit if you have significant additional neurological disease (primary seizure disorder, dementia, Progressive degenerative neurological disorder, Meningitis or encephalitis, Hydrocephalus associated with increased intracranial pressure).

Do not use the Optune Gio treatment kit if you are known to be sensitive to conductive hydrogels like the gel used on electrocardiogram (ECG) stickers or transcutaneous electrical nerve stimulation (TENS) electrodes. In this case, skin contact with the gel used with the Optune Gio treatment kit may commonly cause increased redness and itching, and rarely may even lead to severe allergic reactions such as shock and respiratory failure.

Do not use Optune Gio if you have an active implanted medical device, a skull defect (such as, missing bone with no replacement) or bullet fragments. Examples of active electronic devices include deep brain stimulators, spinal cord stimulators, vagus nerve stimulators, pacemakers and defibrillators. Use of the Optune Gio treatment kit together with implanted electronic devices has not been tested and may lead to malfunctioning of the implanted device. Use of the Optune Gio treatment kit together with skull defects or bullet fragments has not been tested and may possibly lead to tissue damage or render treatment ineffective.

WARNINGS

Warning - Use the Optune Gio treatment kit only after receiving training from qualified personnel, such as your doctor, a nurse, other medical personnel, or Novocure Device Support Specialist who have completed a training course given by the device manufacturer (Novocure). Your training will include a detailed review of this manual and practice in the use of the treatment kit. In addition, you will be trained in what to do if there are problems with treatment. Use of the treatment kit without receiving this training can result in breaks in treatment and may rarely cause increased scalp rash, open sores on your head, allergic reactions or even an electric shock.

Warning - Do not use the Optune Gio treatment kit if you are younger than 18 years of age. It is unknown what side effects the device may cause in these cases or if it will be effective.

Warning - In case of skin irritation, which appears as redness under the transducer arrays (a mild rash), talk to your physician before starting any treatment for skin irritation. Your physician may recommend using over-the-counter topical steroids when replacing transducer arrays. This will help relieve your skin irritation. If you do not use this cream, the skin irritation can become more serious and may even lead to skin break down, infections, pain and blisters. If this happens, stop using the topical steroid cream and contact your doctor. Your doctor will supply you with an antibiotic cream to use when replacing transducer arrays. If you do not use this cream, your symptoms may continue and your doctor may ask you to take a break from treatment until your skin heals. Taking a break from treatment may lower your chance to respond to treatment.

Warning - All servicing procedures must be performed by qualified and trained personnel. If you attempt to open and service the treatment kit alone you may cause damage to the treatment kit. You could also get an electric shock by touching the inner parts of the device.

Warning - No modification of this equipment is allowed.

Warning – Re-use of the Optune HFE transducer arrays can lead to poor contact with the scalp and may cause the device to alarm and stop working. Re-use of the Optune HFE transducer arrays can lead to the worsening of the skin inflammation and rarely even to local infection. If you suffer from an infection on your scalp (pus, swelling and warmth) consult with your physician immediately.

PRECAUTIONS

Caution - Keep the Optune Gio treatment kit out of the reach of children and pets.

Caution - Do not use any parts that do not come with the Optune Gio treatment kit or that were not sent to you by the device manufacturer or given to you by your doctor.

Caution - Do not use the Optune Gio treatment kit if any parts look damaged (torn wires, loose connectors, loose sockets, cracks or breaks in the plastic case).

Caution - Do not wet the device or the Optune HFE transducer arrays. Getting the device wet may damage it, preventing you from receiving treatment for the right amount of time. Getting the Optune HFE transducer arrays very wet is likely to cause the Optune HFE transducer arrays to come loose from your head. If this happens, the device will operate the notification signal and you will need to change the Optune HFE transducer arrays.

Caution - Before connecting or disconnecting the Optune HFE transducer arrays, make sure that the Optune Gio power switch is in the OFF position. Disconnecting the Optune HFE transducer arrays when the device is running will cause a device notification signal to go off, and could damage the device.

Caution – The connection cable may pose a hazard of strangulation. Avoid wearing the connection cable around your neck.

Caution – There is a hazard of falling due to entanglement in the connection cable. You may consider clipping the cable to your belt.

NOTICES

Notice! The Optune Gio treatment kit is to be used with the Optune HFE transducer arrays only.

Notice! The Optune Gio treatment kit and the Optune HFE transducer arrays will activate metal detectors.

Notice! You should use the Optune Gio treatment kit for at least 18 hours a day to get the best response to treatment. Using the Optune Gio treatment kit for less than 18 hours a day lowers the chances that you will respond to treatment.

Notice! Do not stop using the Optune Gio treatment kit even if you have used it less than the recommended 18 hours per day. You should stop using the Optune Gio treatment kit only if your doctor tells you to. Stopping treatment could lower the chances that you will respond to treatment.

Notice! If you plan to be away from home for more than 2 hours, carry a spare battery and/or the power supply with you in case the battery you are using runs out. If you do not take a spare battery and/or the power supply you may have a break in your treatment. Breaks in treatment may lower your chance to respond to treatment.

Notice! Batteries may weaken over time and need to be replaced. You will know this has happened when the amount of time the Optune Gio device can run on a fully charged battery begins to shorten. For example, if the low battery indicator lights up within only 1.5 hours from the start of treatment, replace the battery. If you do not have replacement batteries when your batteries run out, you may have a break in your treatment. Breaks in treatment may lower your chance to respond to treatment.

Notice! Do not block the vents located on the front and back of the Optune Gio device. Blocking the vents may cause the device to overheat and operate the notification signal, leading to a break in treatment. If this happens, unblock the vents, wait 5 minutes and restart the device.

Notice! Do not block the battery charger vents located on the left and right sides of the battery charger. Blocking the vents may cause the charger to overheat. This could prevent your batteries from charging.

4. CLINICAL BENEFIT & CLINICAL EVIDENCE

Patients using the Optune Gio treatment kit after their tumor reappeared lived a similar amount of time compared to patients using cancer drugs. In the clinical study, half of the patients in both groups lived for more than 6.4 months. 22 out of every 100 patients lived for one year or longer.

Patients using the Optune Gio treatment kit after their tumor reappeared had a better quality of life.

Below is a table showing the effects on the benefit of the Optune Gio treatment kit, when it is used correctly or incorrectly after the tumor reappeared.

Benefit from Correct and Incorrect Use of Optune Gio

Event	Likelihood of Event	Outcome	Likelihood of Outcome
Correct use			
Use of the device for at least 18 hours a day	85 out of 98 subjects (87%)	Survival 3 months longer compared to subjects treated less than 18 hours a day	81 out of 85 (95%)
Incorrect use			
Use of the device for less than 18 hours a day	13 out of 98 subjects (13%)	Survival 3 months shorter compared to subjects treated at least 18 hours a day	12 out of 13 (92%)
Wetting the device or soaking the transducer arrays	Unknown	Treatment break	Unknown
Handling of the device by children	Unknown	Treatment break	Unknown

In the clinical study using the Optune Gio treatment kit with temozolomide before patients' tumors reappeared, the time from the start of treatment to death was measured when half of the patients had joined the study as well as at the time when all of the total 695 patients had joined the study. The table below shows the amount of time that patients who used the Optune Gio treatment kit with temozolomide were observed to be alive longer than patients who used temozolomide alone.

	Benefit of Optune Gio + Temozolomide	
	Half of Patients in Study	All Patients in Study
Correct use	Almost 5 months longer	Almost 7 months longer
All subjects	3 months longer	Almost 5 months longer

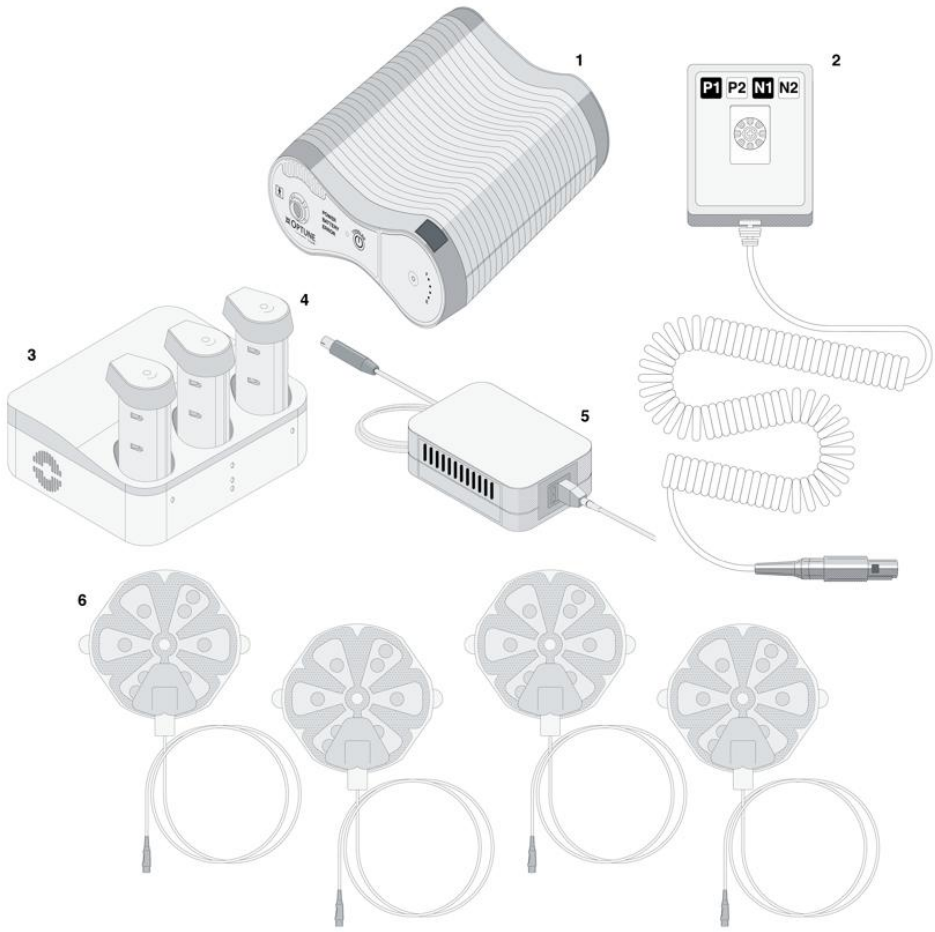
In addition, more patients who used the Optune Gio treatment kit with temozolomide were alive after 2 years than patients using temozolomide alone.

	Patients Alive 2 Years after the Start of Treatment (Optune Gio + Temozolomide vs. Temozolomide Alone)	
	Half of Patients in Study	All Patients in Study
Correct use	48% vs. 32%	43% vs. 25%
All subjects	48% vs. 34%	43% vs. 31%

5. WHAT ARE THE RISKS OF USING THE OPTUNE GIO TREATMENT KIT AND OPTUNE HFE TRANSDUCER ARRAYS?

Skin irritation may be seen under the Optune HFE transducer arrays when using the Optune Gio treatment kit. This will look like a red rash, small sores or blisters on your scalp. In general, the Optune Gio treatment kit will not cause skin damage that cannot be fixed. The irritation can be treated with topical steroid cream or by moving the Optune HFE transducer arrays. If you do not use the topical steroid cream, the skin irritation could become more serious. This may lead to open sores, infections, pain and blisters. If this happens, stop using the steroid cream and contact your doctor.

6. OVERVIEW OF THE OPTUNE GIO TREATMENT KIT



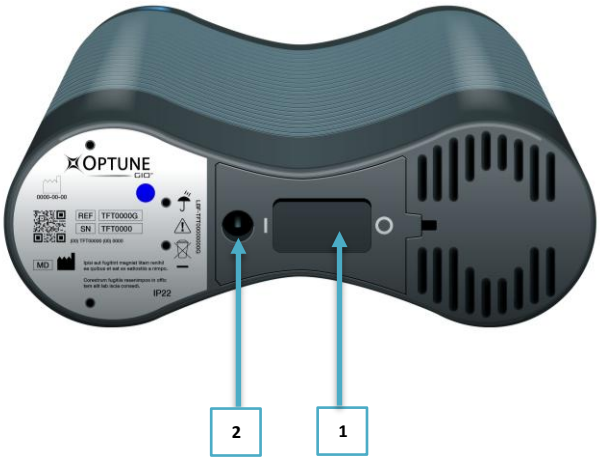
1. Electric field generator (Optune Gio; the Device) (Model TFH9100)
2. Connection cable & box (Model CAD9100)
3. Charger for batteries (Model ICH9100)
4. Battery (Model IBH9100)
5. Plug in power supply (Model SPS9100)
6. Optune HFE transducer array (Model IHEP9020 & IHEP9020W)

7. THE DEVICE

The Optune Gio treatment kit treatment parameters are preset and cannot be changed by the patient. TTFields treatment should be kept on as continuously as possible (24 hours a day, 7 days a week). Although 100% treatment time is impossible, breaks from treatment should be kept as short as possible.

You will need to learn how to place it in a carrying bag, connect a battery and operate the treatment kit.

The following controls will allow you to operate the Optune Gio device:





1 Optune Gio power switch

2 Power Supply Connection cable socket

3 TTFields ON/OFF button

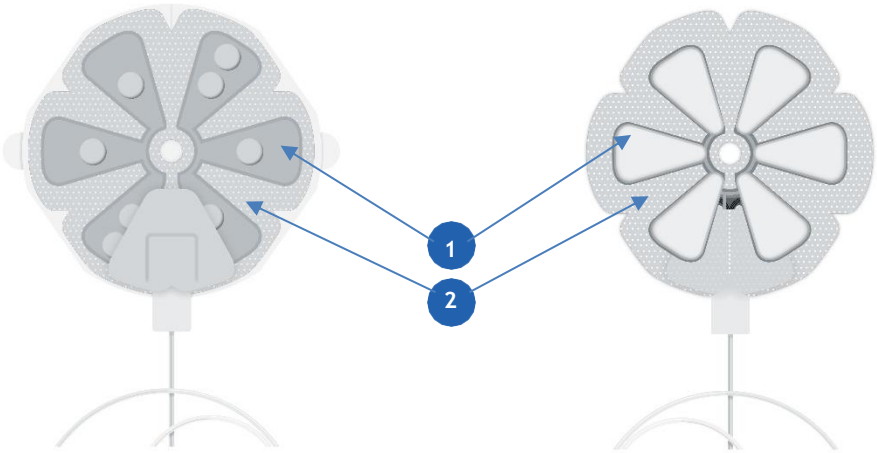
4 Power ON/ Error / Low Battery indicator

5 Connection Cable (CAD) socket

6 Battery Gauge

7 Battery Charge Indicator Button

8. BEFORE YOU BEGIN



Optune HFE Transducer Array

1. Segment
2. Tape

You will need to use four (4) Optune HFE transducer arrays at one time. Change the 4 Optune HFE transducer arrays twice a week to continue treatment with the Optune Gio treatment kit. You may change the Optune HFE transducer arrays with the help of a doctor, a nurse or caregiver if needed.

Make sure you have an adequate supply of the Optune HFE transducer arrays to keep you going until your next visit to your physician.

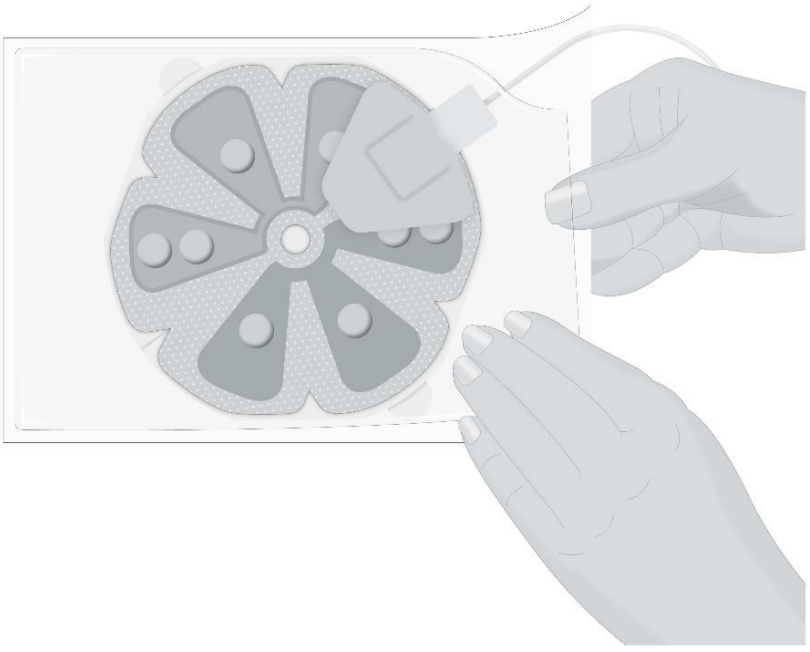
Before using the Optune HFE transducer array make sure its package is sealed. Do not use an Optune HFE transducer array package which has been opened previously.

Although the transducer arrays are provided in individual sterile packages to minimize infection risk, you and/or your caregiver can take additional steps to further reduce the risk of infection: Always wash your hands prior to application and removal of the transducer arrays; Wash your scalp between transducer array exchanges; Clean the electric razor per manufacturer's guidelines after every shave.

The Optune HFE transducer arrays are provided sterile for single use.

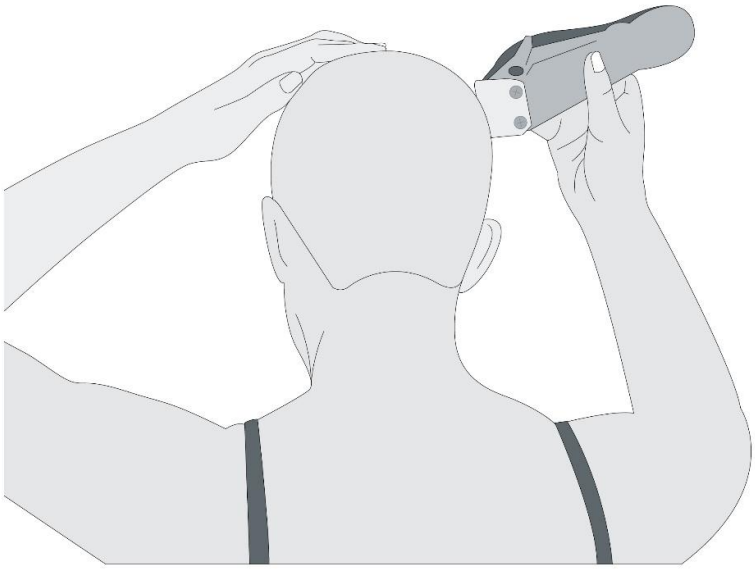
9. REMOVING THE OPTUNE HFE TRANSDUCER ARRAY FROM ITS PACKAGE

- Wash your hands before opening the package with the Optune HFE transducer array.
- Open the see through package of each of the four (4) Optune HFE transducer arrays by gently pulling apart the opposing edges of the package as shown in the illustration.



10. PREPARING YOUR HEAD FOR THE OPTUNE HFE TRANSDUCER ARRAY PLACEMENT

- Wash your head with a gentle shampoo.
- If this is the first time you are using the Optune HFE transducer arrays, ignore this step and skip ahead to the next step (shaving).
- If you are replacing the Optune HFE transducer arrays, you, or your doctor or caregiver if needed, should wipe the skin with baby oil to remove any remaining adhesive from previous Optune HFE transducer arrays. Baby oil is used to remove remaining adhesive. It will not stop the device from working.
- Shave your entire scalp using an electric shaver. Do not leave any stubble. Wipe your scalp with 70% Alcohol (available at your local pharmacy without a prescription).
- Use an over-the-counter hydrocortisone (steroid) cream if your scalp is red. Treat open sores on your scalp like your doctor told you. If you use this cream, wait at least 15 minutes to ensure skin penetration. Any residues may be removed by cleaning the skin and wipe your scalp again with 70% Alcohol. Apply the Optune HFE transducer arrays after your scalp is dry.



11. PLACING THE OPTUNE HFE TRANSDUCER ARRAYS ON YOUR HEAD

After you have prepared your scalp (Section 10), put the Optune HFE transducer arrays on your head with the help of a doctor or caregiver if needed. Twice a week, remove the Optune HFE transducer arrays, prepare the scalp (as outlined in Section 10) and put on a new set of Optune HFE transducer arrays. You will know it is time to change the Optune HFE transducer arrays when the device alarm beeps persistently. This means that the device is not able to work properly because of hair growth. Hair growth keeps the Optune HFE transducer arrays from making good contact with your scalp.

To place the Optune HFE transducer arrays on your head, with the help of a caregiver or doctor if needed, follow the steps below. Note, if this is the first time you are using the Optune HFE transducer arrays, ignore the first step (removal).

- Remove the Optune HFE transducer arrays from your head by carefully and slowly peeling the medical tape away from your scalp.

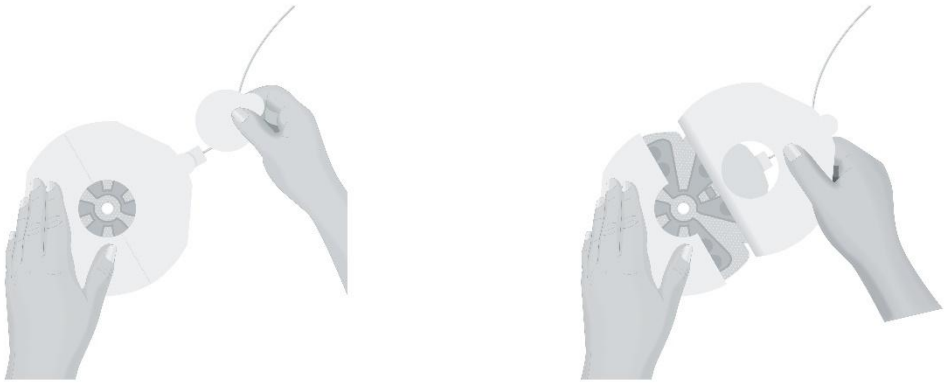
In the treatment kit, there are Optune HFE transducer arrays with two connector colors– black and white.

- Note on the transducer array layout the location where each transducer array color should be placed on your head. The Optune HFE transducer array locations and colors are: front & back (black), left & right (white).
- Prepare your skin for the Optune HFE transducer arrays, as described in Section 10.
- Peel off the three (3) white liners covering the gel from the first Optune HFE transducer array.

NOTICE: make sure there is no transparent cover is over the gel. In case there is, carefully remove before proceeding.

- Pull the tabs on each side of the Optune HFE transducer arrays and press them firmly to your scalp. Press the entire edge of the Optune HFE transducer array tape to your scalp.

Optune HFE transducer array liner removal



- Remove the white outer liners.

The flexible polymer material can be damaged by cutting the Optune HFE transducer arrays.

Do not use the Optune HFE transducer arrays if the gel is damaged or the flexible polymer area is damaged on the top or back of the Optune HFE transducer arrays.

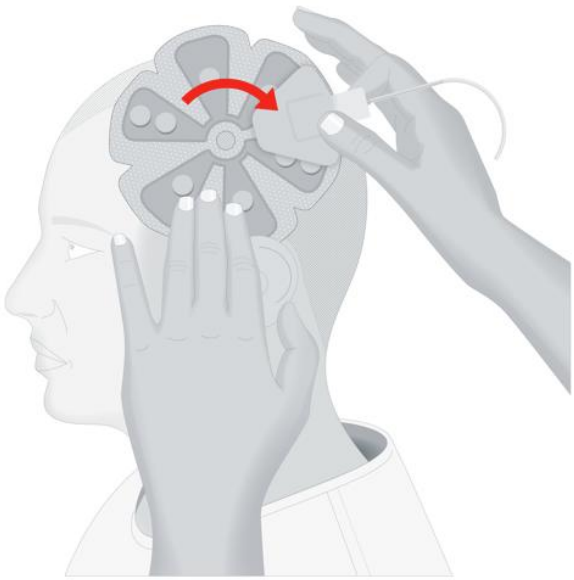
- Remove all liners covering the gel areas before applying the Optune HFE transducer arrays to the scalp.

- Put the Optune HFE transducer arrays on your head as shown in the Optune HFE transducer array layout map that you received. Placement is based on the location of your tumor.



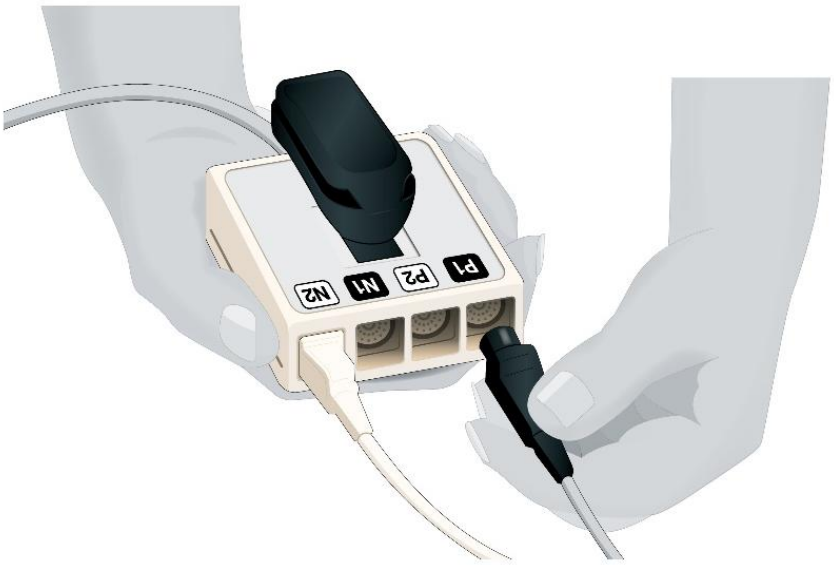
- The Optune HFE transducer arrays should have approximately 2cm separation from each other (one finger width) during application to reduce the likelihood of skin irritation.

- To reduce skin irritation under the Optune HFE transducer arrays, move or rotate the Optune HFE transducer arrays slightly. Place the other three Optune HFE transducer arrays in the same way. Press the Optune HFE transducer array firmly to your scalp. Press the entire edge of the Optune HFE transducer array tape to your scalp.



12. CONNECTING THE OPTUNE HFE TRANSDUCER ARRAYS TO THE DEVICE

- Connect each of the four Optune HFE transducer array connectors with the black or white connector to the matching color socket on the connection cable box. For example, plug the Optune HFE transducer array with the black connector into the black socket (labeled "N1"; see diagram).
- Connect the other three Optune HFE transducer array connectors in the same way.
- Press firmly to ensure the connectors are pushed in all the way. Hold the Optune HFE transducer array wires together. Wrap them with a small piece of tape, if you wish.
- You may clip the connection cable to your belt.



13. STARTING AND STOPPING THE DEVICE

To start treatment, connect a power source - either a charged battery or a power supply (see Section 15 or 16) to the device.

- Press the power switch on the bottom of the device to the on position.



- Wait approximately 10 seconds for the self-check to be completed. The "Power" indicator on the front of the device will light up green.



If a charged battery is installed and there is no power supply plugged in, the "Battery" indicator will also light up green.



If a power supply, connected to the mains, is plugged into the device, the device will run from the power supply and the "Battery" indicator will not illuminate.

- Press the TTFields ON/OFF button once – this will start treatment.



The blue indicators surrounding the TTFields ON/OFF button will light up and remain on for as long as treatment continues.

Note: The green, blue and yellow indicators will dim in a dark room and will brighten in a light environment. The red error indicator light will not be dimmed in any case

If the TTFields button is not pressed within several minutes after the device is turned ON, a notification signal will sound, indicating that the device is ON but the treatment is OFF. This is a reminder to start the treatment. The TTFields button should be pressed once to silence the notification signal and again to start the treatment.

Stopping treatment may be performed in each of the following situations:

a) When the device is running properly:

- Press the TTFields button – The blue indicator surrounding the TTFields ON/OFF button will turn off.



- Then, turn off the device by turning the power button on the bottom of the device to the off position.



b) If an Error Occurs:

If an error occurs, the device will turn off the TTFields and make a loud beeping noise. The red Error light will light up.

To turn off the device:

- Press the TTFields button on the front of the device to stop the notification signal. The red Error light will turn off.
- Turn off the device by pressing the power button to the off position.
- See the Troubleshooting Guide (Section 24) for instructions on fixing problems.
- Restart the device and restart treatment if no problem is found. If the notification signal does not stop, contact technical support (Section 26).

c) When the Low Battery indicator lights up:

When the battery has about 20% power left the “Battery” indicator will turn yellow, alerting that you will need to change the battery soon.



When the battery runs out (after about 2–3 hours), the notification signal will beep, and the TTFields treatment will stop. When this happens the "Battery" indicator will turn yellow and red Error light will light up. However, in this case both the yellow "Battery" and red "Error" indicators will light up instead of just the red light.



To turn off the device:

- Press the TTFields button on the front of the device to stop the notification signal. The red Error and the yellow Battery lights will turn off.
- Turn off the device using the on/off power switch.
- Replace the battery using the steps in Section 14.

14. CONNECTING & DISCONNECTING THE BATTERY

The Optune Gio treatment kit comes with 4 rechargeable batteries. Batteries slide into the device, while the blue buttons on both sides of the battery are being held. The battery should be inserted until there is a "click", indicating the battery is in place. Take care not to drop the battery in place or to force it into the battery slot.

The Optune Gio device uses one (1) battery at a time. The other three (3) batteries should stay in the battery charger. Each battery lasts 2 to 3 hours. Replace the battery each time it runs out (when the yellow Low Battery indicator light is on, as described in Section 15). If you plan to be away from home for more than 2 hours, carry extra batteries or the power supply provided with the Optune Gio treatment kit.



- Gently press down to lock the battery in place. Make sure the battery latch is fully engaged.



To remove the battery from the slot, press both blue buttons on the side of the battery and slide up until removed.



Recharge the batteries in the charger (see Section 15) for four to five hours. The batteries will stay charged if they are off the charger for a short time (hours, but not days). For this reason, keep the extra batteries in the charger at all times, if possible.

- You can charge and use the batteries many times.

Over nine to twelve months, the length of time the batteries can run the device (before the low battery notification signal beeps) will get shorter. When this happens, contact technical support (see Section 26) to get replacement batteries.

When the yellow Low Battery indicator light lights up, there are two ways you can replace the depleted battery with a charged battery.

Option One: To be used if near the direct wall power supply. This allows you to change the battery without interrupting treatment. This can be used before the battery is completely depleted, and before the device has operated the notification signal. Please follow these steps:

- Plug the power supply cord into the back of the Optune Gio device. (See Section 16)
- The lights on the display panel will indicate you are no longer running on battery power.
- Remove the battery from the battery slot by pressing on the blue buttons on the side of the battery and sliding the battery out of the battery slot.
- Slide the fully charged battery in the battery slot, gently push down to lock in place.
- Remove the power supply cord from the bottom of the device.

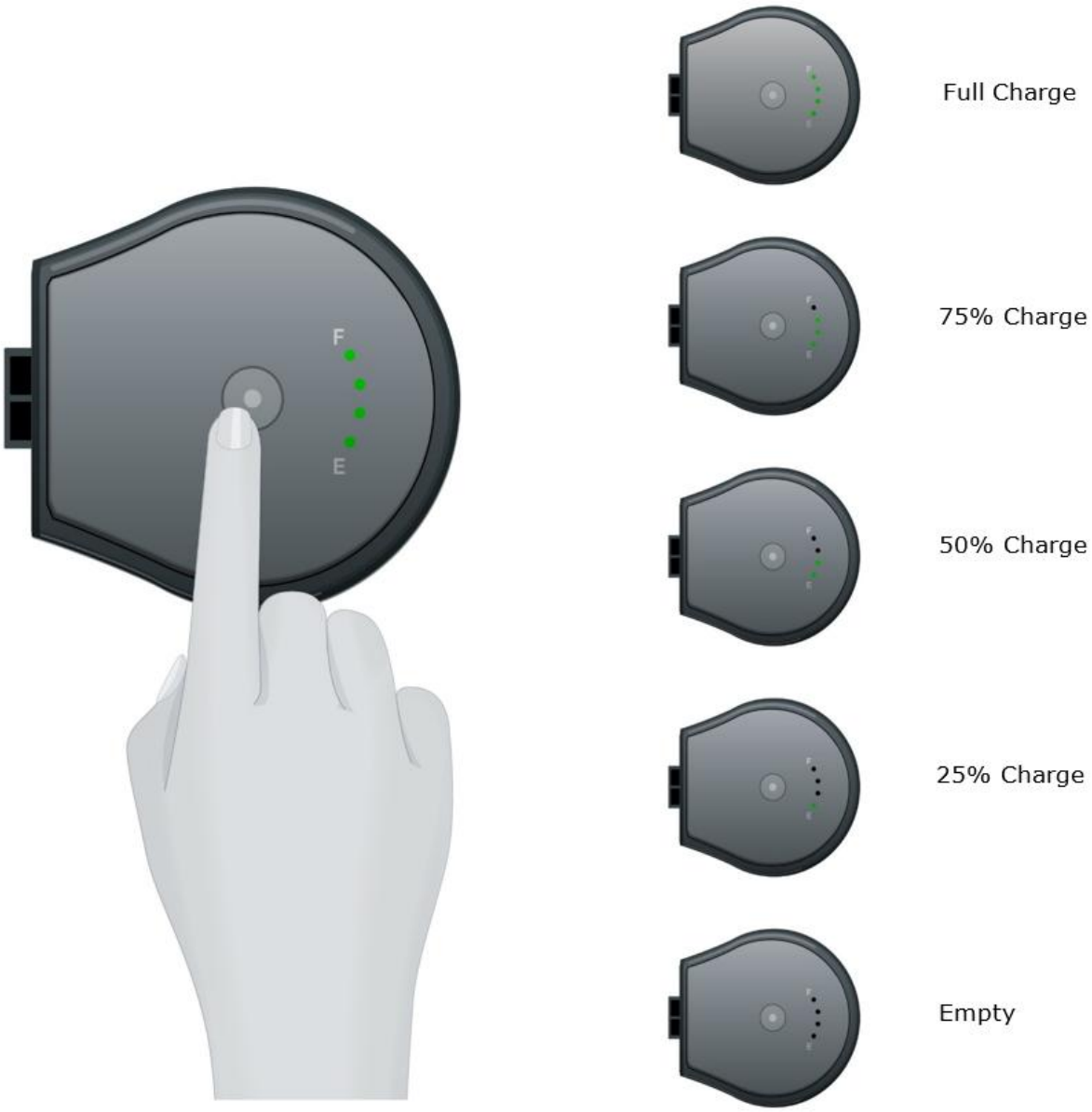
Option Two: If you are not near the power supply, or if the battery has totally depleted please replace the battery using these steps:

- Turn off the notification signal by pressing the TTFields button once.
- Turn off the device using the power switch (on the back of the device).
- Remove the battery from the battery slot by pressing on the blue buttons on the side of the battery and sliding the battery out of the battery slot.
- Slide the fully charged battery in the battery slot, gently push down to lock in place.
- Turn on the device and start treatment by pressing the power button, wait for the system to run a self-check (this takes about 10 seconds), then press the TTFields button (see Section 7).
- Place the used battery in the charger for recharging (as described in Section 15).

Checking the Battery Gauge

While you are using Optune Gio, you may want to check how much power is left in the battery. Checking the battery will not interfere with or stop your treatment.

To check the battery power press the button on the top of the battery cartridge once. The remaining battery power will be indicated by the readout to the right of the button. The gauge reads from full to empty, like a gas gauge in your car.



15. CHARGING THE BATTERY

The battery charger recharges used batteries. The battery charger uses power from a standard wall outlet.

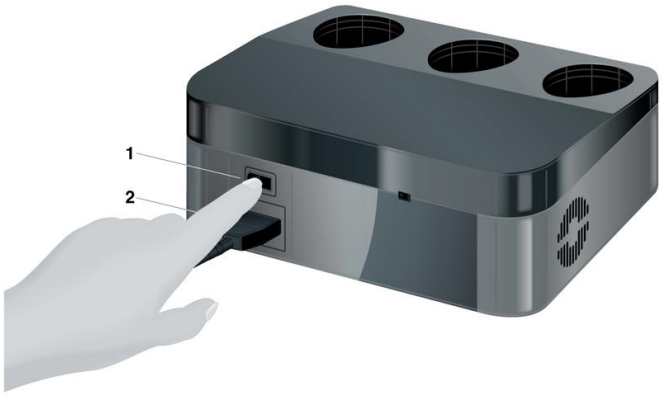
Before charging the batteries, plug the charger power cord into a standard wall outlet and turn on the power button at the back of the charger. The small light in the center of the front panel will light up green indicating power is applied.

To recharge a used battery:

- Place the used battery in one of the three openings in the top of the charger. Push down on the battery until it is fully inserted into the slot.
- The light directly in front of the opening where the battery is plugged in will illuminate flashing green. The flashing green indicates that the battery is charging. The light will flash faster when the battery reaches approximately 80% of a full charge.
- When the battery is fully charged (about 4 to 5 hours), the charge light will turn from blinking green to solid green. The solid green light will disappear on removal of the battery or the disconnection of the charger from the mains socket.

If the light in front of the opening turns red, this indicates that there is a fault with the battery and you should contact technical support to have it replaced. Do not use a battery if it creates a red light on the charger.

Keep the batteries in the charger even after they are fully charged. This will not harm the batteries.



1 Power Switch

2 Charger Mains Cable

Back view of the battery charger showing where to turn the charger on and off and where to connect the charger power cord



1 Battery

2 Charger opening

3 Charger Indicator

Front view of the battery charger showing how the batteries are installed in the charger

Notice: The charger is considered to be disconnected from the mains only when the power cable is physically disconnected either from the mains or from the charger itself.

Notice: The charger is considered class II equipment, without signal input/ output and applied part (part which come into physical contact with the patient). Mode of operation - continuous operation. The charger is not intended for use in the presence of flammable mixtures.

Sterilization or disinfection are not required.

16. USING THE POWER SUPPLY

When you plan to stay in one place for a while, such as when you are sleeping, you may use the plug-in power supply instead of the batteries. Unlike the batteries, there is no limit to how long the device can work when you use the plug-in power supply. The plug-in power supply will work with either U.S. (120V AC) or European (230V AC) outlets.

Note: It is normal for the power supply to become warm when in use. If the power supply becomes too hot to touch, unplug it and contact technical support (Section 26).

When the power supply is plugged in, the device will utilize the power supply as the preferred power source. If it is running, it will automatically switch from battery power to plug-in power supply.



AC Port located next to the power switch

Connecting the Plug-In Power Supply

1. Plug in the power supply to a standard wall outlet using the power cord that comes with the treatment kit.
2. You do not need to remove the battery from the device to use the plug in power supply. Please note that a battery in the device will not charge when plugged into the plug-in power supply. Depleted batteries must be placed on the battery charger to re-charge. If the TTFields are activated you do not need to turn them off to plug in the power supply.
3. Plug the round connector of the plug-in power supply cable into the round socket AC port on the back of the device (next to the power button).
4. If the TTFields are running, the device will switch to power supply power without interruption of the TTFields. If the device is not turned on, turn on the power switch and wait for the self-check to be completed (about 10 seconds). Push the TTFields button to start the device (as described in Section 13).

To Disconnect the Plug-In Power Supply and Return to Battery Power

1. Ensure that a charged battery is properly installed in the device before removing the power supply. If the TTFields are running, you do not need to turn them off before removing the plug-in power supply. The device will automatically switch to battery power once the power supply is removed.
2. Remove the connector of the plug-in power supply from the socket on the back of the device.
3. If the device is not turned on, turn on the power switch and wait for the self-check to be completed (about 10 seconds). Push the TTFields button to start the treatment.
4. Store the plug-in power supply for future use.



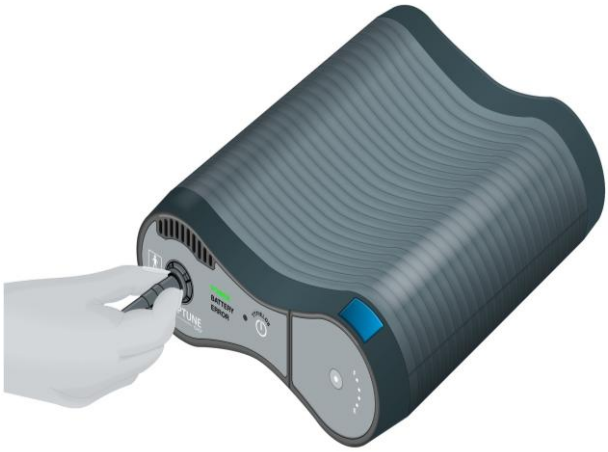
17. THE CONNECTION CABLE & BOX

The connection cable is the coiled, stretchy cord that runs from the device to the connection box. The four Optune HFE transducer array connectors (2 black and 2 white) plug into the connection box. The black and white coding matches with the Optune HFE transducer array position on the head, black to the back and front, white to the either side.

The connection cable plugs into the device in the socket on the left of the front panel. The connection cable socket has a picture of a person next to it and a white ring around it. The connection cable plugs into the socket with the arrow on the connector facing up. Push in the connector until you hear a snap. The snap means it is in the right place.

Note: It is important that the arrow on the connection cable face up and is aligned with the arrow on the connector socket on the device. Do not force the connection cable into the socket. It should push in easily if properly aligned.





There are two ways to unplug from the device to take a break from treatment (after turning off the device):

1. Unplug the connection cable from the device.
2. Unplug the Optune HFE transducer arrays from the connection cable box.

To unplug the connection cable from the device:

Stop treatment by pressing the TTFields ON/OFF button. Turn off the device using the power button.

Unplug the connection cable from the socket by holding the sleeve and pulling. Do not pull on the cord.

You may now move around without the device, but you will still be connected to the connection cable and box. To start treatment again after your break:

1. Plug the connection cable into the connection cable socket with the arrow pointing up.
2. Turn on the device using the power button. Wait for self-check to be completed (about 10 seconds).
3. Turn on the TTFields using the TTFields ON/OFF button.

To unplug the Optune HFE transducer arrays from the connection cable:

To take a break from treatment and completely disconnect from the device but leave the Optune HFE transducer arrays on your head, unplug the Optune HFE transducer array cables from the connection cable box. The four Optune HFE transducer arrays are plugged into the connection cable box as described in Section 12. The connection cable is plugged into the device at the connection cable socket.

1. Stop treatment by pressing the TTFields ON/OFF button.
2. Turn off the Optune Gio device using the power button.
3. Unplug the Optune HFE transducer array connectors from the connection box by pulling as shown in the picture below. You may have to wiggle the Optune HFE transducer array cables to remove them.
   To restart treatment, plug the Optune HFE transducer arrays into the connection box. Plug each Optune HFE transducer array into its matching color (black or white) that goes with the Optune HFE transducer array's position on the head (see earlier in this section 12).
4. When all 4 Optune HFE transducer arrays are plugged in, turn on the power switch and wait for self-check to be completed (about 10 seconds). Push the TTFields ON/OFF button to restart treatment.



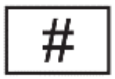
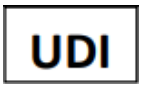
18. CARRYING THE DEVICE

The electric field generator with the installed battery will fit in the shoulder bag or the backpack. The bag or backpack can be carried in four ways: by the handle on top or over the shoulder or cross-body with a carrying strap attached or as a backpack.

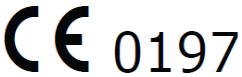
Note: Do not place the device in a different bag. Optune Gio has a fan that needs airflow. The bag that comes with the device is designed to allow for proper airflow. If you put the device in a bag without proper airflow, it could overheat and trigger the notification signal.



19. GLOSSARY OF SYMBOLS

	Follow instructions for use
	Medical device
	Manufacturer information: Novocure GmbH, Neuhofstrasse 21, 6340 Baar, Switzerland
	Model number
	Reference Number
	Serial Number
	Lot Number
	Unique Device Identifier Indicates a device carries Unique Device Identifying information.
	Manufacture Date
 YYYY-MM	Use-by date/Expiry date
	Caution Consult the instructions for use for important cautionary information such as warnings and precautions
	Waste Electrical and Electronic Equipment recycling "WEEEE disposal" Contact technical support to arrange for proper disposal of Optune HFE transducer arrays that are used up or no longer in use.

	Batteries are Lithium Ion. Contact technical support to arrange for proper disposal of batteries that are used up or no longer in use.
	Do not re-use: The Optune HFE transducer arrays are for single use and should not be re-used
	Indicates that the packaged products are sterile, the products have been sterilized by irradiation and the packaging is a single sterile barrier system
	Sterile/sterilization method The Optune HFE transducer arrays are sterilized by Gamma irradiation
	Do not re-sterilize
	Do not use if package is damaged. Do not use the Optune HFE transducer arrays if their packaging is breached
	Protect from heat and radioactive sources
IPxx	International Protection Rating (IP) code: A coding system to indicate the degrees of protection provided by an enclosure against access to hazardous parts or water. IP21: Optune Gio Power supply protects persons against access to hazardous parts with fingers. Protects the equipment inside the enclosure against ingress of solid foreign objects of 12.5 mm in diameter or greater and against ingress of vertical falling water drops. IP22: Optune Gio device protects persons against access to hazardous parts with fingers. Protects the equipment inside the enclosure against ingress of solid foreign objects of 12.5 mm in diameter or greater and against ingress of vertical falling water drops when enclosure is tilted up to 15°.
	Keep dry. Do not expose the Optune HFE transducer arrays to water. Do not enter rooms with high humidity or danger of direct exposure to water while wearing the device.
	For indoor use only

	Class II equipment per IEC 60601-1
	BF type applied part Symbolizes the part which comes in contact with the patient
	Storage Temperature range The storage temperature range for the Optune HFE Tranducer Arrays is 5°C and 27°C and -5°C and 40°C for the device
	Storage humidity range. Do not expose to humidity below 15% or above 93% (device and additional parts) Do not expose to humidity below 10% or above 90% (Optune HFE transducer arrays)
	Fragile, handle with care
	MR UNSAFE
	CE Mark with Notified Body Number
	European authorized representative MDSS GmbH Schiffgraben 41 30175 Hanover, Germany
	Importer details: Novocure Netherlands B.V., Ekkersrijt 2066, 5692 BA Son en Breugel, The Netherlands
	Power ON / OFF switch for the Optune Gio device and the battery charger: When the switch is in the I position the device is ON and will light up green. When the switch is in the O position the device is OFF

20. ENVIRONMENTAL CONDITIONS FOR OPERATION, STORAGE AND TRANSPORTATION

Conditions for operation

- All treatment kit components shall be normally used under the conditions specified below:
- The treatment kit is intended mainly for home use.
- The battery charger and the power supply are for indoor use only.
- The device, additional parts and Optune HFE transducer arrays are not intended for use in a shower, a bath tub, a sink or in heavy rain. Also they are not for use in the presence of flammable mixtures.
- If any treatment kit parts are dropped on the floor, there is no safety hazard, but they are not expected to function anymore.

Conditions of visibility

Any.

Cleaning

All external treatment kit components can be periodically cleaned with a damp cloth, to remove dust and regular soil. Avoid using detergents or soaps.

Physical operation conditions for all treatment kit components

- Temperature range: -5°C to +40°C
- Relative humidity range: 15-93%
- Ambient pressure range: 700-1060hPa

Conditions for storage

- Temperature range: -5°C to +40°C for the device and additional parts
- Temperature range: 5°C to +27°C for the Optune HFE transducer arrays
- Relative humidity range: 15-93% for the device and additional parts
- Relative humidity range: 10-90% for the Optune HFE transducer arrays

Conditions for transport

Transportation of the device and additional parts shall be possible using air/ ground transportation in weather protected conditions as specified below:

- Temperature range: -5°C to +40°C
- Maximal relative humidity: 15-93%
- No direct exposure to water

Transportation of the Optune HFE transducer arrays shall be possible using air/ground transportation in weather-protected conditions as specified below:

- Temperature range: 0°C to 40°C
- No direct exposure to water

21. TRAVELLING WITH OPTUNE GIO

- Contact your Device Support Specialist if you plan to travel and if you have questions related to travel restrictions. His/her contact information will be supplied to you separately.
- The batteries contain lithium ion and are restricted from being checked as luggage for passenger aircraft travel. They can be carried in the passenger cabin. Check with Novocure if you have any questions related to travel restrictions.
- When traveling to other country with the Optune Gio device, use the suitable electric cable that was provided with the Optune Gio treatment kit. Travel adapters should not to be used with the Optune Gio treatment kit.

22. EXPECTED PRODUCT LIFE

The expected product life for the Optune Gio device and all components of the treatment kit is 5 years.

The expected product life of the Optune HFE transducer arrays is 9 months. The Optune HFE transducer arrays have an expiration date. Please do not use the arrays after the expiration date.

23. DISPOSAL

- Contact Novocure to arrange for proper disposal of used Optune HFE transducer arrays. Do not throw them in the trash. Novocure contacts local authorities for the determination of proper disposal method for potentially biohazardous parts.
- All devices should be returned to Novocure. Contact Novocure to arrange for return.

24. TROUBLESHOOTING

Note, when calling your device support specialist or the Technical Support line, please have the serial number of the equipment accessible.

Problem	Possible Causes	Actions to be Taken
Redness of the skin beneath the Optune HFE transducer arrays	Common side effect	1. Use hydrocortisone cream prescribed by your doctor when replacing the Optune HFE transducer arrays. 2. Place Optune HFE transducer arrays in a location shifted by 2 cm from the last location (so the adhesive gel is between the red marks). **If the redness gets worse:** See your treating doctor.
Blisters beneath the Optune HFE transducer arrays	Rare side effect	See your treating doctor.
Itching beneath the Optune HFE transducer arrays	Rare side effect	1. Use hydrocortisone cream prescribed by your doctor when replacing the Optune HFE transducer arrays. 2. Place Optune HFE transducer arrays in a location shifted by 2 cm from the last location (so the adhesive gel is between the red marks). **If the itching gets worse:** See your treating doctor.
Pain under the Optune HFE transducer arrays	Rare side effect	Stop treatment. See your doctor.
Device power indicator does not light up after turning ON the device	1. Battery dead 2. Battery malfunction 3. Charger malfunction 4. Device malfunction	1. Replace battery. **If problem persists:** 1. Turn OFF power switch 2. Call your Device Support Specialist

Problem	Possible Causes	Actions to be Taken
Any cable detached from the Optune HFE transducer array/ connection cable/device	1. Excessive physical force to cables 2. Device malfunction 3. Damaged connector	1. Silence the notification signal by pressing the TTFields button and stopping treatment. 2. Evaluate the connectors, if intact – reconnect and re-start therapy. 3. If anything appears damaged or cannot be properly connected do not try to use the device. Please reach out to your DSS Device Support Specialist.
Device dropped or got wet	Incorrect use	1. Press TTFields button to stop treatment. 2. Turn OFF power switch 3. Call your Device Support Specialist
One of the items was dropped, opened or got wet	Incorrect use	If you are on therapy using the damaged item – stop the therapy, power the device down and reach out to your device support specialist.
Device alarm on or Error Indicator on	1. Low battery 2. Cable becoming loose or disconnected 3. The device is too hot 4. Vents being blocked 5. Local hot spot on Optune HFE transducer array from laying on a pillow or other insulator 6. Poor Optune HFE transducer array contact due to hair growth or other reason 7. Device malfunction 8. Damaged Array 9. Connection box malfunction	**If Low Battery indicator is yellow:** 1. Silence the notification signal by pressing the TTFields ON/OFF button 2. Turn the device off completely 3. Replace the battery with a fully charged one. 4. Turn on treatment **If the Error indicator lights up but the Low Battery indicator is green or off :** 1. Press the TTFields ON/OFF button to stop the alarm 2. Wait a few seconds then press the TTFields ON/OFF button again to re-start treatment. 3. If the three blue lights around the TTFields treatment button illuminate - the treatment has now been activated **If the notification signal recurs:** 1. Stop the notification signal and turn the device off completely. 2. Disconnect all plugs and make sure that nothing appears to be loose, damaged or broken. 3. If something is damaged, replace the damaged item.

Problem	Possible Causes	Actions to be Taken
		4. Reconnect all connections in proper order and turn on the device. Verify that the self- test is completed and press the TTFields ON/OFF Button. 5. Check vents on device and charger to make sure they are not blocked 6. If lying down, move your head 7. Make sure the Optune HFE transducer arrays are stuck securely to the head with each disc making direct skin contact, add tape if needed. If contact seems to be no longer optimal, replace the arrays. 8. If you are in a hot environment try moving to a cooler place or turning a fan on and 9. Restart treatment 10. If the alarm keeps going off, turn off the device and contact your Device Support Specialist
Notification signal sounds several minutes after the device was powered on	Treatment Timeout	1. The device will initiate the notification signal at a different frequency if it is turned on for several minutes but treatment is not initiated. 2. This is a reminder for you to start therapy and does not indicate a malfunction. 3. Silence the notification signal by pressing the TTFields button then wait a few seconds and press the TTFields button again. The blue indicator around the TTFields button will blink and then stay on to indicate therapy is now on.
Low Battery indicator remains on after battery replaced or if battery gauge is showing the battery is full	1. Charger malfunction 2. Battery malfunction 3. Device malfunction	1. Replace the battery with a fully charged battery. 2. Place the original battery in the battery charger. 3. If the problem persists across multiple batteries OR if one of the batteries will not charge or causes the charger LED to turn red – call your Device Support Specialist.

Problem	Possible Causes	Actions to be Taken
When powering the device on a continuous notification signal sounds and all lights remain on indefinitely. Device does not complete the self-test	1. Device is too hot 2. Device malfunction 3. Power source malfunction	1. Turn the device off completely using the main switch. 2. Verify that the device is not hot to the touch. 3. Connect the device to a different power source and try to turn the device on. 4. If the device cannot be turned on by either the battery or the power supply or if anything appears to be damaged, please reach out to your device support specialist.
When powering the device on none of the lights come on	1. Device not connected to Power source 2. If battery –battery depleted 3. If power supply – not properly plugged into the wall 4. Device malfunction 5. Power source malfunction	1. If on battery, check battery fuel gauge to verify it is not depleted. If it is, replace with a fully charged battery or the power supply. 2. Verify both the device and the power source are properly connected and re-try. 3. Evaluate the integrity of all connectors. Nothing should appear to be damaged or broken in any way. If the device cannot be turned on by either the battery or the power supply or if anything appears to be damaged, please reach out to your device support specialist.

25. EXPECTED SERVICE LIFE

Expected service life reflects the average time during which the equipment specified below is expected to work without malfunctioning. Please continue using the equipment if it passed its expected service life and do not stop the treatment.

Optune Gio device and additional parts expected service life is as below:

- Optune Gio device – 12 months
- Connection cable – 11 months
- Power supply – 5 years
- Battery – 11 months (or until the expiration date)
- Charger – 7 years

26. ASSISTANCE & INFORMATION

Technical support:

For technical support, contact your Device Support Specialist. His/her contact information will be supplied to you separately.

If you are unable to get a hold of your Device Support Specialist, you can contact the EMEA Novocure technical support email: patientinfoEMEA@novocure.com or SupportEMEA@novocure.com

Please state the following information in your query:

NAME: (First/Last)

EMAIL:

TELEPHONE: (optional)

COUNTRY:

QUESTION:

Clinical support:

If you feel any change in your health or any side effects from the treatment call your doctor.

REPORTING

If you experience a serious incident that occurs while using the Optune Gio treatment kit or the Optune HFE transducer arrays you should report it to the manufacturer (Novocure) DeviceSafety@Novocure.com and the competent authority of the Member State in which you reside.

27. GLOSSARY

Cancer – abnormal cell division that spreads without control

Chemotherapy – medication used to destroy cancer cells

Clinical trial – a research study that involves people

Contraindications – situations when a treatment should not be used

WHO grade 4 glioma – a type of brain cancer

Optune HFE transducer array – array of insulated transducers applied to the scalp to deliver the TTFields.

Local – in one part of the body

MRI scan – a procedure that uses a magnet to create pictures of areas inside the body

Optune Gio – (also called TTFields generator or NovoTTF-200A device) – A portable device for delivering TTFields to the brain of patients with recurrent or newly diagnosed WHO grade 4 glioma.

EN 60601-1 – Harmonized standards series for safety of medical electrical equipment

28. APPLICABLE STANDARDS

The Optune Gio treatment kit electronic components and the sterile transducer arrays comply with the latest editions of the following safety standards:

- EN 60601-1 Medical electrical equipment — Part 1: General requirements for basic safety and essential performance
- EN 60601-1-2 Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests
- EN 60601-1-11- Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- EN 60601-1-6 Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral Standard: Usability
- EN 62366-1 Medical devices — Part 1: Application of usability engineering to medical devices
- EN 62304 - Medical device software — Software life-cycle processes

29. INPUT OUTPUT SPECIFICATIONS

The Optune Gio treatment kit including the battery charger are considered class II equipment according to EN 60601-1.

Mode of operation – continuous. The device is portable when battery operated and stationary equipment when connected to the power supply.

The applied part is classified as BF.

The treatment kit is not intended for use in the presence of flammable mixtures.

Disinfection is not required.

The Optune HFE transducer arrays are provided sterile for single use.

Battery for Optune Gio (Li-Ion Rechargeable)
OUTPUT 29.6 ⎓ 94.7Wh

Charger for Optune Gio

INPUT 100-240V ~ 1.5A 50/60Hz OUTPUT 3X33.6 V ⎓ 1.3A

Power supply for Optune Gio

INPUT 100-240V ~ 1.1A 50/60Hz OUTPUT 28 V ⎓ 2.9A

30. EMITTED RADIATION & ELECTROMAGNETIC COMPATIBILITY

The Optune Gio treatment kit, the accompanying battery charger (ICH9100) and power supply (SPS9100) need special precautions regarding EMC and need to be installed and put into service according to the EMC information provided below.

Portable and mobile RF communications equipment can affect the Optune Gio treatment kit and the accompanying battery charger.

The Optune Gio device should be used with the following cables and additional parts only:

1. CAD9100 connection cable
2. IHEP9020 Optune HFE transducer array (Sterile)
3. IBH9100 battery
4. SPS9100 power supply
5. ICH9100 charger
6. Unshielded AC mains cables for indoor use only with a maximal length of 1.5m

The use of accessories, parts and cables other than those specified, may result in increased EMISSIONS or decreased IMMUNITY of the Optune Gio treatment kit.

Table 1 – Guidance and MANUFACTURER'S declaration – ELECTROMAGNETIC EMISSIONS – for all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer's declaration – electromagnetic emissions		
The Optune Gio treatment kit is intended for use in the electromagnetic environment specified below. the customer or the user of the Optune Gio treatment kit should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Optune Gio treatment kit uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Optune Gio treatment kit is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic emissions		
The ICH9100 charger and the SPS9100 power supply are intended for use in the electromagnetic environment specified below. The customer or the user of the ICH9100 charger and the SPS9100 power supply should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The ICH9100 charger and the SPS9100 power supply use RF energy only for their internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The ICH9100 charger and the SPS9100 power supply are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Warning: The Optune Gio device, the ICH9100 charger and the SPS9100 power supply should not be used adjacent to or stacked with other equipment

Table 2 – Guidance and MANUFACTURER'S declaration – ELECTROMAGNETIC IMMUNITY – for all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer's declaration – electromagnetic immunity			
The Optune Gio treatment kit is intended for use in the electromagnetic environment specified below. The customer or the user of the Optune Gio treatment kit should ensure that it is used in such an environment.			
Emissions test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact, ± 2 kV, ± 4 kV, ±8 kV, ± 15 kV air	±8 kV contact, ± 2 kV, ± 4 kV, ±8 kV ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines 100 kHz repetition	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0,5 kV, ±1 kV line to line ± 0,5 kV, ± 1 kV, ±2 kV line to ground	± 0,5 kV, ±1 kV line to line ± 0,5 kV, ± 1 kV, ±2 kV line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The ICH9100 charger and the SPS9100 power supply are intended for use in the electromagnetic environment specified below. The customer or the user of the ICH9100 charger and the SPS9100 power supply should ensure that they are used in such an environment.			
Emissions test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0,5 kV, ± 1 kV line to line ± 0,5 kV, ± 1 kV, ± 2 kV line to ground	± 0,5 kV, ± 1 kV line to line ± 0,5 kV, ± 1 kV, ± 2 kV line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles h) Single phase: at 0° 0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level = 120V and 230V			

Table 3 – Guidance and MANUFACTURER'S declaration – ELECTROMAGNETIC IMMUNITY – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration – electromagnetic immunity			
The Optune Gio treatment kit is intended for use in the electromagnetic environment specified below. The customer or the user of the Optune Gio treatment kit should ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz (table 8.5.1) 10 V/m	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz 10 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the Optune Gio treatment kit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \frac{6}{E}\sqrt{P}$ Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m. Field strengths from fixed RF transmitters, as deter-mined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated fields in close proximity Standard IEC 61000-4-39	8A/m 30kHz CW 65A/m 134.2kHz pulse modulated 2.1kHz 7.5A/m 13.56MHz pulse modulated 50kHz	5cm distance	
NOTE These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Optune Gio treatment kit is used exceeds the applicable RF compliance level above, the Optune Gio treatment kit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Optune Gio treatment kit.

Guidance and manufacturer's declaration – electromagnetic immunity			
The ICH9100 charger and the SPS9100 power supply are intended for use in the electromagnetic environment specified below. The customer or the user of the ICH9100 charger and the SPS9100 power supply should ensure that they are used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz (table 8.5.1) 10 V/m	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz 10 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the ICH9100 charger and the SPS9100 power supply, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \frac{6}{E}\sqrt{P}$ Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ICH9100 charger and the SPS9100 power supply are used exceeds the applicable RF compliance level above, the ICH9100 charger and the SPS9100 power supply should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ICH9100 charger and the SPS9100 power supply.

Normal operation: The Optune Gio treatment kit is working properly when the blue LED surrounding the TTFields button are lit and no notification signal sounds. The ICH9100 charger is working properly when all the LEDs are lit. The SPS9100 power supply is working properly when the blue LEDs surrounding the TTFields button on Optune Gio treatment kit are lit and no notification signal sounds.

Table 4 – Recommended separation distances between portable and mobile RF communications equipment and the ME EQUIPMENT or ME SYSTEMS – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m						
	380 – 390MHz	430 – 470MHz	704 – 787MHz	800 – 960MHz	1700 – 1990MHz	2400 – 2570MHz	5100 – 5800MHz
The Optune Gio treatment kit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Optune Gio treatment kit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Optune Gio treatment kit as recommended below, according to the maximum output power of the communications equipment.							
0.2	0.3	0.3	0.3	0.3	0.3	0.3	0.3
1.8	0.3	0.3	0.3	0.3	0.3	0.3	0.3
2	0.3	0.3	0.3	0.3	0.3	0.3	0.3
NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.							
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.							

Manufactured by Novocure GmbH
Neuhofstrasse 21, 6340 Baar, Switzerland

EC REP MDSS GmbH, Schiffgraben 41,
30175 Hannover, Germany

Importer details:
Novocure Netherlands B.V., Ekkersrijt 2066, 5692 BA Son en Breugel,
The Netherlands

CE 0197

QSD-QR-084 EU(EN) Rev02

manuals.novocure.eu